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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,288	04/01/2004	Michael Carl Junger	PA-5386-RFB	8573
9896	7590	12/23/2005	EXAMINER	
COOK GROUP PATENT OFFICE P.O. BOX 2269 BLOOMINGTON, IN 47402			BOUCHELLE, LAURA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TMA

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/816,288	JUNGER, MICHAEL CARL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura A. Bouchelle	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 11, 13, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinosa et al (US 4634420). Spinosa discloses a separable flushing and aspiration needle; the flushing assembly comprising a needle 42 connectable to a source of flushing liquid 20; the aspiration assembly comprising a needle 14 connectable to an aspiration arrangement (See Abstract); and the aspiration needle extends coaxially within the flushing needle. See Fig. 1.
3. Spinosa discloses a handle 8, and outer needle 42 extending from the handle, a side port 98 connectable with a source of flushing liquid, an aspiration assemble comprising a proximal portion 56 connectable to an aspiration assembly, and a connection 58 arranged to join the aspiration assembly to the handle (Col. 10, lines 25-43). See Fig. 1.
4. Spinosa discloses a first connector portion 47 on the handle and a second connector portion 58 on the aspiration cannula; and the aspiration cannula having a grip portion 56 that

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extends into the connector portion in use. See Fig. 1. Spinosa discloses that the connector portions are snap in locks (Col. 5, lines 35-38).

5. The tapered extension further comprises alignment detents 43, which engage with corresponding recesses on the connector portion. See Fig. 3. The connector portion further comprises an internally tapered wall. See Fig. 2.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al in view Emery et al (US 5160319). Claim 6 differs from Spinosa in calling for the outer needle to have a beveled tip. Emery teaches an oocyte retrieval needle comprising an outer needle with a beveled tip 68 allowing the physician to precisely puncture the follicle and release the oocyte (Col. 4, lines 55-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinosa to have a bevel as taught by Emery to allow the physician to precisely puncture the follicle and release the oocyte.

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8. Claim 8 differs from the teachings above in calling for the distal end of the aspiration tip to terminate just within the beveled end of the outer needle. Claim 9 calls for the distal end to terminate between 0.5 and 1.5 mm proximally from the base of the beveled tip. Emery teaches an aspiration cannula 36 located within an outer cannula 30 wherein the aspiration cannula ends just proximal the beveled tip of the outer cannula so that rotation of the needle scrapes the follicle wall to dislodge the oocyte so that it can be aspirated (Col. 5, lines 34-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Spinoso so that the distal end of the aspiration tip to terminate just within the beveled end of the outer needle as taught by Emery so that rotation of the needle scrapes the follicle wall to dislodge the oocyte so that it can be aspirated.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Emery et al as applied to claim 6 above, and further in view of West et al (US 6273877). Claim 7 differs in calling for the tip to further include a secondary bevel. West teaches a needle having a tip with a primary bevel and a secondary bevel that provide a sufficiently sharp distal end to penetrate the skin with little risk of excessive force urging the needle too far into the body (Col. 3, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinoso in view of Emery to have a secondary bevel as taught by West to provide a sufficiently sharp distal end to penetrate the skin with little risk of excessive force urging the needle too far into the body.

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10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al in view of Davis et al (US 6018676). Claim 10 differs from Spinosa in calling for a portion at the distal end of the outer needle to be treated to improve its ultrasound echo characteristics. Davis teaches a needle comprising indenting, patterning or knurling to increase echogenicity of the needle (Col. 2, lines 35-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinosa to have indenting, patterning or knurling as taught by Davis to increase its echogenicity.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al in view of Mottola et al (US 5533986). Claim 11 differs from Spinosa in calling for an O-ring on the connector portion. Mottola teaches the use of an O-ring to form a fluid tight seal between two separable parts of a catheter (Col. 9, lines 30-33). Furthermore, it is well known in the art to use an O-ring to ensure a fluid tight seal between two connectable parts. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the connector portion of Spinosa to include an O-ring as taught by Mottola to ensure a fluid tight seal between the two connecting portions.

12. Claim 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al in view of Knox (US 3561596). Claim 16 differs from Spinosa in calling for the assembly to be supplied in a sterile peel open package. Claim 17 differs in calling for the assembly to be provided in a disassembled state. Knox teaches a packaging for syringes, needles and the like wherein each element of a device can be supplied as a separate unit in an individual peel apart

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package that can be easily opened and kept sterile before use (Col. 4, lines 13-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Spinoso to be in a disassembled state in peel apart sterile packages as taught by Knox so that the package can be easily opened and kept sterile before use.

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso et al in view of Emery as applied to claim 6 above, and further in view of and Davis. Claim 18 differs from Spinoso in calling for a beveled tip. Emery teaches an oocyte retrieval needle comprising an outer needle with a beveled tip 68 allowing the physician to precisely puncture the follicle and release the oocyte (Col. 4, lines 55-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinoso to have a bevel as taught by Emery to allow the physician to precisely puncture the follicle and release the oocyte.

14. Claim 18 further differs from the teachings above in calling for the needle to be treated to improve ultrasound echo characteristics. Davis teaches a needle comprising indenting, patterning or knurling to increase echogenicity of the needle (Col. 2, lines 35-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinoso to have indenting, patterning or knurling as taught by Davis to increase its echogenicity.

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***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle  
Examiner  
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